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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/591,632 06/09/00 LINDQUIST

S 27373/34978A

EXAMINER

HM12/1002

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BRANNOCK, M

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/591,632

Applicant(s)

Lindquist et al.

Examiner

Michael Brannock, Ph.D.

Art Unit

1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 7, 19, 20, 22, 24-32, 38, 41, 42, 46, 48, 49, 55-58, 60, 61, 63, 64 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1, 2, 4, 7, 19, 20, 22, 24-32, 38, 41, 42, 46, 48, 49, 55-58 are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, 4, 7, 19, 20, 22, 24-32, 46, 48, 61 and 97, drawn to polynucleotides and chimeric polypeptides, classified in class 536, subclass 23.5.
  - II. Claims 38, 41 and 42, drawn to methods of modifying a cell such that polypeptide fibrils are produced in the cell, classified in class 435, subclass 252.3.
  - III. Claim 49, 75, 86, 90-93, drawn to methods of making a composition comprising polypeptide fibrils, classified in class 530, subclass 402.
  - IV. Claims 55-58, 60, 61, 63, 65, 66 and 67, drawn to methods of making a reactive SCAG amino acid sequence, classified in class 435, subclass 69.1.

2. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups II-IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group II requires modifying a cell to produce an intracellular fibril, which is not required by any of the other groups. Group III requires in vitro methods of constructing fibrils, which is not required by any of the other groups.

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Group IV requires methods of identifying amino acid residues of a polypeptide that are responsible for aggregation, which is not required by any of the other groups.

The polynucleotides and chimeric polypeptides of Group I are related to the methods of Groups II-IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides and chimeric polypeptides of Group I are patentably distinct from each of the methods of Groups II-IV because the polynucleotides and chimeric polypeptides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups II-IV are materially and functionally distinct from the others.

3. Claims 1, 2, 4, 7, 19, 20, 22, 24-32, 38, 41, 42, 46, 48, 49, 55-58, 60, 61, 63, 65-67, 75, 81, 86, 90-93 and 97 are generic to a practically limitless plurality of disclosed patentably distinct species comprising a multitude of polynucleotides and encoded fusion polypeptides, each polynucleotide and encoded fusion protein being a structurally and functionally distinct set of molecules, the use of one particular polynucleotide and encoded fusion protein not being required for the use of any other. Further, a search of one could not be relied upon to provide art that is anticipatory of any other, and to search more than one polynucleotide and encoded polypeptide in a single application would be burdensome.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of polynucleotide and encoded fusion polypeptide, such species having a single defined polynucleotide sequence encoding a defined polypeptide sequence, for prosecution on the merits, even though this requirement is traversed.

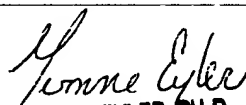
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

MB

  
September 28, 2001

  
YVONNE EYLER, PH.D.  
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